SCIG (immune globulin SQ): Hizentra®, Gammagard Liquid®, Gamunex®-C, Gammaked®, Hyqvia®, Cuvitru®, Cutaquig®, Xembify® (Subcutaneous)

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I. Length of Authorization

Initial coverage will be provided for 6 months and may be renewed annually thereafter.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

Drug Name	Dose/ week	Dose/28 days
Hizentra	46 g	184 g
Gamunex-C & Gammaked	24 g	96 g
Gammagard liquid	24 g	96 g
HyQvia	17.5 g	69 g
Cuvitru	23 g	92 g
Cutaquig	24 g	96 g
Xembify	24 g	96 g

B. Max Units (per dose and over time) [HCPCS Unit]:

Drug Name	Billable units/28 days
Hizentra	960 (PID)
	1840 (CIDP)
Gamunex-C & Gammaked	192
Gammagard liquid	192
HyQvia	690
Cuvitru	920
Cutaquig	960
Xembify	960

III. Initial Approval Criteria [1-8, 15,18]

Coverage is provided in the following conditions:

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**

Primary immunodeficiency (PID)/Wiskott -Aldrich syndrome †

Such as: x-linked agammaglobulinemia, common variable immunodeficiency, transient hypogammaglobulinemia of infancy, IgG subclass deficiency with or without IgA deficiency, antibody deficiency with near normal immunoglobulin levels) and combined deficiencies (severe combined immunodeficiencies, ataxia-telangiectasia, x-linked lymphoproliferative syndrome) *[list not all inclusive]*

- Patient is ≥ 2 years old [HyQvia ONLY: patient must be ≥ 18 years old]; **AND**
- Patient's IgG level is <200 mg/dL **OR** both of the following:
    - Patient has a history of multiple hard to treat infections as indicated by at least **one** of the following:
        - Four or more ear infections within 1 year
        - Two or more serious sinus infections within 1 year
        - Two or more months of antibiotics with little effect
        - Two or more pneumonias within 1 year
        - Recurrent or deep skin abscesses
        - Need for intravenous antibiotics to clear infections
        - Two or more deep-seated infections including septicemia; **AND**
    - The patient has a deficiency in producing antibodies in response to vaccination; **AND**
        - Titers were drawn before challenging with vaccination; **AND**
        - Titers were drawn between 4 and 8 weeks of vaccination

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [Hizentra ONLY] † Φ

- Patient must be ≥ 18 years old; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.); **AND**
    - Used as initial maintenance therapy for prevention of disease relapses after treatment and stabilization with intravenous immunoglobulin (IVIG)**§**; **OR**
    - Used for re-initiation of maintenance therapy after experiencing a relapse and requiring re-induction therapy with IVIG (see Section IV for criteria)

Acquired Immune Deficiency secondary to Chronic Lymphocytic Leukemia ‡ [31,32]

- Patient's IgG level is <200 mg/dL **OR** both of the following:

- Patient has a history of multiple hard to treat infections as indicated by at least **one** of the following:
  - Four or more ear infections within 1 year
  - Two or more serious sinus infections within 1 year
  - Two or more months of antibiotics with little effect
  - Two or more pneumonias within 1 year
  - Recurrent or deep skin abscesses
  - Need for intravenous antibiotics to clear infections
  - Two or more deep-seated infections including septicemia; **AND**
- The patient has a deficiency in producing antibodies in response to vaccination; **AND**
  - Titers were drawn before challenging with vaccination; **AND**
  - Titers were drawn between 4 and 8 weeks of vaccination

Note: other secondary immunodeficiencies resulting in hypogammaglobulinemia and/or B-cell aplasia will be evaluated on a case-by-case basis

§ Refer to the Immune Globulins medical necessity criteria (Document Number: IC-0071) for the relevant intravenous criteria requirements

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1-8, 15,18]

Coverage can be renewed for 1 year based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity/anaphylaxis, thrombosis, aseptic meningitis syndrome, hemolytic anemia, hyperproteinemia, acute lung injury, etc.; **AND**
- BUN and serum creatinine obtained within the last 6 months and the concentration and rate of infusion have been adjusted accordingly; **AND**

Primary immunodeficiency (PID)/Wiskott -Aldrich syndrome

- Disease response as evidenced by one or more of the following:
  - Decrease in the frequency of infection
  - Decrease in the severity of infection

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [Hizentra ONLY]

- Renewals will be authorized for patients that have demonstrated a beneficial clinical response to maintenance therapy, without relapses, based on an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.); **OR**
- Patient is re-initiating maintenance therapy after experiencing a relapse while on Hizentra; **AND**
  - Patient improved and stabilized on IVIG treatment: **AND**
  - Patient was NOT receiving maximum dosing of Hizentra prior to relapse

Acquired Immune Deficiency secondary to Chronic Lymphocytic Leukemia [31,32]

- Disease response as evidenced by one or more of the following:
  - Decrease in the frequency of infection
  - Decrease in the severity of infection; **AND**
- Patient is at a decreased risk of infection as a result of treatment necessitating continued therapy

V. Dosage/Administration

Dosing should be calculated using adjusted body weight if one or more of the following criteria are met:

- Patient's body mass index (BMI) is 30 kg/m^2 or more; **OR**
- Patient's actual body weight is 20% higher than his or her ideal body weight (IBW)

Use the following dosing formulas to calculate the adjusted body weight (round dose to nearest 5 gram increment in adult patients)
Dosing formulas
BMI = 703 x (weight in pounds/height in inches^2)
IBW(kg) for males = 50 + [2.3 (height in inches – 60)]
IBW(kg) for females = 45.5 + [2.3 x (height in inches – 60)]
Adjusted body weight = IBW + 0.5 (actual body weight – IBW)

This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide. Patient-specific variables should be taken into account.

Indication	Dose
Chronic Inflammatory Demyelinating Polyneuropathy	<u>Hizentra ONLY:</u> ▪ Initiate therapy 1 week after the last IVIG dose ▪ The recommended subcutaneous dose is 0.2 g/kg (1 mL/kg) body weight per week, administered in 1 or 2 sessions over 1 or 2 consecutive days. ▪ If CIDP symptoms worsen, consider increasing the dose to 0.4 g/kg (2 mL/kg) body weight per week, administered in 2 sessions over 1 or 2 consecutive days. ▪ If CIDP symptoms worsen on the 0.4 g/kg body weight per week dose, consider re-initiating therapy with an IVIG while discontinuing Hizentra.

Indication	Dose
Primary immune deficiency including Wiskott-Aldrich Syndrome AND Acquired Immune Deficiency secondary to Chronic Lymphocytic Leukemia	<u>Hizentra</u>: ▪ Switching from IVIG o Initiate therapy 1 week after the last IVIG dose o Weekly dose: 1.37*(previous IVIG dose (g)/number of weeks between IVIG doses) o May be administered from daily up to every two weeks (biweekly) o Biweekly dose: twice the weekly dose (using calculation above) o Frequent dosing (2-7 times per week): divide the calculated weekly dose by the desired number of times per week ▪ Switching from SCIG o Initiate therapy 1 week after the last SCIG dose o Weekly dose (in grams) should be same as the weekly dose of prior SCIG treatment (in grams) o Biweekly dose: multiply the calculated weekly dose by 2 o Frequent dosing (2-7 times per week): divide the calculated weekly dose by the desired number of times per week
	<u>Gamunex-C/Gammaked/Gammagard Liquid</u>: ▪ Initiate therapy 1 week after the last IVIG dose ▪ Weekly dose: 1.37*(previous IVIG dose(g)/number of weeks between IVIG doses)
	<u>HyQvia</u>: ▪ Naïve to IgG or switching from SCIG: 300 to 600 mg/kg at 3 to 4 week intervals after initial ramp-up* ▪ Switching from IGIV: use the same dose and frequency as the previous IV treatment after initial ramp-up* ***NOTE:*** *For patients previously on another IgG treatment, initiate therapy 1 week after the last infusion of IVIG or SCIG*
	<u>Xembify:</u> ▪ Switching from IVIG o Start treatment one week after the last IVIG infusion. o Weekly dose: 1.37*(previous monthly (or every 3- week) IVIG dose in grams)/number of weeks between IVIG doses) ▪ Switching from SCIG o Weekly dose (in grams) should be same as the weekly dose of prior SCIG treatment (in grams)
	<u>Cuvitru:</u> ▪ Switching from IVIG or HyQvia o Initiate therapy 1 week after the last IVIG or Hyqvia dose o Weekly dose: 1.30*(previous IVIG or HyQvia dose (g)/number of weeks between IVIG or HyQvia doses) o May be administered from daily up to every two weeks (biweekly)

Indication	Dose
	○ Biweekly dose: twice the weekly dose (using calculation above) ○ Frequent dosing (2-7 times per week): divide the calculated weekly dose by the desired number of times per week ▪ Switching from SCIG ○ Weekly dose (in grams) should be same as the weekly dose of prior SCIG treatment (in grams) ○ May be administered from daily up to every two weeks (biweekly) ○ Biweekly dose: multiply the calculated weekly dose by 2 ○ Frequent dosing (2-7 times per week): divide the calculated weekly dose by the desired number of times per week
	Cutaquig: ***NOTE:*** *Start treatment one week after the last IVIG or SCIG infusion. Ensure that patients have received IVIG or SCIG treatment at regular intervals for at least 3 months* ▪ Switching from IVIG ○ Weekly dose: 1.30*(previous IVIG dose (g)/number of weeks between IVIG doses) ○ May be administered from daily up to every two weeks (biweekly) ○ Biweekly dose: multiply the calculated weekly dose by 2 ○ Frequent dosing (2-7 times per week): divide the calculated weekly dose by the desired number of times per week ▪ Switching from SCIG ○ Weekly dose (in grams) should be same as the weekly dose of prior SCIG treatment (in grams) ○ May be administered from daily up to every two weeks (biweekly) ○ Biweekly dose: multiply the calculated weekly dose by 2 ○ Frequent dosing (2-7 times per week): divide the calculated weekly dose by the desired number of times per week

Dosing for immunoglobulin products is highly variable depending on numerous patient specific factors, indication(s), and the specific product selected. For specific dosing regimens refer to current prescribing literature.

*HyQvia initial treatment interval/dosage ramp-up schedule

Week	Infusion Number	3-week treatment interval	4-week treatment interval
1	1st infusion	Dose in Grams X 0.33	Dose in Grams X 0.25
2	2nd infusion	Dose in Grams X 0.67	Dose in Grams X 0.50
4	3rd infusion	Total Dose in Grams	Dose in Grams X 0.75
7	4th infusion	N/A	Total Dose in Grams

VI. Billing Code/Availability Information

HCPCS Code & NDC(s):

Drug Name*	Manufacturer	HCPCS Code	1 Billable unit	NDC	IgG (grams) per SDV	Volume (mL)
Hizentra 20% (Vials)	CSL Behring AG	J1559 – Injection, immune globulin (Hizentra), 100 mg	100 mg	44206-0451-01	1	5
				44206-0452-02	2	10
				44206-0454-04	4	20
				44206-0455-10	10	50
Hizentra 20% (Prefilled Syringes)	CSL Behring AG	J1559 – Injection, immune globulin (Hizentra), 100 mg	100 mg	44206-0456-21	1	5
				44206-0457-22	2	10
				44206-0458-24	4	20
Gammaked 10%	Grifols Therapeutics	J1561 – Injection, immune globulin, (Gamunex-C/ Gammaked), non-lyophilized (e.g., liquid), 500 mg	500 mg	76125-0900-01	1	10
				76125-0900-25	2.5	25
				76125-0900-50	5	50
				76125-0900-10	10	100
				76125-0900-20	20	200
Gamunex-C 10%	Grifols Therapeutics	J1561 – Injection, immune globulin, (Gamunex-C/Gammaked), non-lyophilized (e.g., liquid), 500 mg	500 mg	13533-0800-12	1	10
				13533-0800-15	2.5	25
				13533-0800-20	5	50
				13533-0800-71	10	100
				13533-0800-24	20	200
				13533-0800-40	40	400
Gammagard Liquid 10%	Baxalta US Inc.	J1569 – Injection, immune globulin, (Gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg	500 mg	00944-2700-02	1	10
				00944-2700-03	2.5	25
				00944-2700-04	5	50
				00944-2700-05	10	100
				00944-2700-06	20	200
				00944-2700-07	30	300
HyQvia 10% (with Recombinant Human Hyaluronidase 160 U/mL)	Baxalta US Inc.	J1575 – Injection, immune globulin/ hyaluronidase, (Hyqvia), 100 mg immune globulin	100 mg	00944-2510-02	2.5	25
				00944-2511-02	5	50
				00944-2512-02	10	100
				00944-2513-02	20	200
				00944-2514-02	30	300
Cuvitru 20%	Baxalta US Inc.	J1555 – Injection, immune globulin (Cuvitru), 100 mg	100 mg	00944-2850-01	1	5
				00944-2850-03	2	10
				00944-2850-05	4	20
				00944-2850-07	8	40
				00944-2850-09	10	50
Cutaquig 16.5%	Octapharma	J1551 – Injection, immune globulin (cutaquig), 100 mg *(Effective 07/01/2022)*	100 mg	00069-1061-01	1	6
				00069-1802-01	1.65	10
				00069-1476-01	2	12
				00069-1960-01	3.3	20

Drug Name*	Manufacturer	HCPCS Code	1 Billable unit	NDC	IgG (grams) per SDV	Volume (mL)
		J3590 – unclassified biologics *(Discontinue use on 07/01/2022)* C9399 – unclassified drugs or biologicals *(Discontinue use on 07/01/2022)*		00069-1509-01	4	24
				00069-1965-01	8	48
Xembify 20%	Grifols	J1558 – Injection, immune globulin (Xembify), 100 mg	100 mg	13533-0810-05	1	5
				13533-0810-10	2	10
				13533-0810-20	4	20
				13533-0810-50	10	50
Immune Globulin, Human, Subcutaneous	N/A	J3590 – unclassified biologics C9399 – unclassified drugs or biologicals	N/A	N/A	N/A	N/A

**90284 – immune globulin (SCIg), human, for use in subcutaneous infusions*

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31. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, Version 1.2022. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed September 2021.
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Appendix 1 – Covered Diagnosis Codes (All Products)

ICD-10	ICD-10 Description
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.11	Chronic lymphocytic leukemia of B-cell type in remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
D80.0	Hereditary hypogammaglobulinemia
D80.1	Nonfamilial hypogammaglobulinemia
D80.2	Selective deficiency of immunoglobulin A [IgA]
D80.3	Selective deficiency of immunoglobulin G [IgG] subclasses
D80.4	Selective deficiency of immunoglobulin M [IgM]
D80.5	Immunodeficiency with increased immunoglobulin M [IgM]
D80.7	Transient hypogammaglobulinemia of infancy
D81.0	Severe combined immunodeficiency [SCID] with reticular dysgenesis
D81.1	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers

ICD-10	ICD-10 Description
D81.2	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers
D81.6	Major histocompatibility complex class I deficiency
D81.7	Major histocompatibility complex class II deficiency
D81.89	Other combined immunodeficiencies
D81.9	Combined immunodeficiency, unspecified
D82.0	Wiskott-Aldrich syndrome
D83.0	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells
D83.8	Other common variable immunodeficiencies
D83.9	Common variable immunodeficiency, unspecified

Additional covered diagnosis codes applicable to Hizentra ONLY:

ICD-10	ICD-10 Description
G61.81	Chronic inflammatory demyelinating polyneuritis
G61.89	Other inflammatory polyneuropathies
G62.89	Other specified polyneuropathies

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC